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| EXAMINER |
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CLARK, GREGORY D

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| ART UNIT | PAPER NUMBER |
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1786

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08/31/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/518,923 | Applicant(s) BUREAU ET AL. | |
| | Examiner GREGORY CLARK | Art Unit 1786 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24, 26 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25, 27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receiving the applicant's amended claims dated 07/12/2010. Claims: 23, 25, 27, 29 and 30.

Rejections and objections made in previous office action that do not appear below have been overcome by applicant's amendments and therefore the arguments pertaining to these rejections/objections will not be addressed.

Claim Rejections - 35 USC § 103

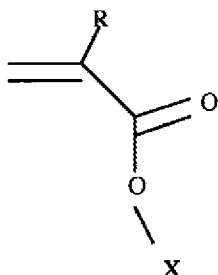
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 23, 25, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand (WO 2002/098926) in view of Crispin (J. Am. Chem. Soc., 1999, Vol. 121, pages 176-187) and Stirling (Advanced Materials, 2000, 12, No. 16, p. 1161-1171).**
2. **Regarding Claim 23**, Bertrand teaches electrografting a strong adherent polymer coating on an electrically conductive surface comprising an electrochemical grafting at the surface of an active monomer (comprising a reactive functional group for attachment of a molecule having at least one complementary reactive group) (Page 5,

Art Unit: 1786

lines 8-11). Bertrand further discloses electrografting involves using an active monomer represented by Formula B-1 (pages 5):



wherein R represents hydrogen or methyl
 and the monomer comprises an X group
 which is part of a preformed polymer or
 is an intermediate agent for polyaddition reaction or
 is an anchoring group for attachment of a molecule having at least one
 complementary reactive group

Formula B-1 represent an electrografted monomer where R is a hydrogen atom or a methyl group which represents an acrylic acid organic precursor or a methacrylic acid organic precursor, respectively. Monomers based on these organic precursors would engage in hydrogen bonding based on the non-bonded electron pair the oxygen atoms.

Bertrand further discloses electrografted coatings of polymers such as polyhydroxyethylacrylate (contains hydroxyl protic groups) can be deposited on the conducting substrates with a strong adhesion and an increased and tunable thickness (controllable thickness) (page 8, lines 18-20).

Although Formula B-1 represent a generic monomer suitable for electrografting, Bertrand fails to mention the organic precursors claimed by applicant.

Crispin discloses the electrografting of acrylate monomer on to metal surface (abstract). Crispin further mentions acrylic acid as a monomer that can be electrografted on to a metal surface.

Whereas Bertrand teaches that acrylate monomers can be electrografted on to metal surfaces and Crispin discloses the acrylic acid can be electrografted on to a metal surface, it would have been obvious to one of ordinary skill in the art at the time of the invention to have selected from known acrylates that had been used for electrografting which would have included acrylic acid as disclosed by Crispin which reads on the instant limitations, absent unexpected results.

Bertrand does not teach electrografting resulting in 90% of the total functional groups being accessible of the functional groups and the density of accessible functional groups of interest is between $10^4/\text{micron}^2$ and $10^{10}/\text{micron}^2$.

Stirling discloses that for a functionalized metal surface composed of an organic layer with a pendant functional group for the immobilization of a biomaterial, steric crowding can decrease the amount of reaction between the functional groups and the biomaterial. Stirling specifically discloses that the reaction rate is substantially diminished with steric crowding around the reaction center (page 1169).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have carried out an electrografting process based on Bertrand by adjusting the level of accessible of the functional groups and the density of the functional groups to account for the expected steric constraints (crowding of the

Art Unit: 1786

functional groups limit reactivity) based on Stirling which would have included the claimed ranges, absent unexpected results.

3. **Regarding Claim 25**, Bertrand teaches that electrografted monomers (Formula B-1, made from methacrylic acid or acrylic acid organic precursors was discussed above) and polyhydroxyethylacrylate (contains hydroxyl protic groups) can undergo controlled or uncontrolled ring opening polymerization (referred to by the applicant as molecules that are cleavable by nucleophilic attack) (page 8, lines 16-31).

4. **Regarding Claim 29**, Bertrand teaches electrografting reactions on steel, stainless steel, Inco316L, tantalum, titanium, nitinol carbon, ITO glass, transition metal (Fe, Ni, Cu, Au, and Ag), metal doped polymers (page 6, lines 30-32).

5. **Regarding Claims 30**, Bertrand teaches electrografting acrylates or methacrylates (made from methacrylic acid or acrylic acid organic precursors was discussed above) containing an anchoring group (X in Formula B-1 above) for direct attachment of a molecule having at least one complementary reactive group (page 5, lines 20-26).

Bertrand also discloses electrografted coatings of polymers such as polyhydroxyethylacrylate (contains hydroxyl protic groups, polymer derived acrylic acid monomer) can be deposited on conducting surfaces (page 8, lines 18-20).

Art Unit: 1786

The process allows the grafting onto the initial coating (adhesion primer) by compounds like functional polymers such as, protein, peptide, oligonucleotide (defined as DNA chips, page 4, line 28), dyes, drugs, and anti-bacterian compounds (page 6, lines 9-11).

Betrand also mentions the use of monomeric species which do not have reactive functional groups such as polystyrene (page 8, line 18) and Bertrand fails to mention a formulation composed of a mixture of monomers with and without a reactive functional group.

Stirling discloses that for a functionalized metal surface composed of an organic layer with a pendant functional group for the immobilization of a biomaterial, steric crowding can decrease the amount of reaction between the functional groups and the biomaterial. Stirling specifically discloses that the reaction rate is substantially diminished with steric crowding around the reaction center (page 1169).

The use of monomers that do not have reactive functional groups is viewed as an obvious means decrease the degree of steric crowding. Functionalized substrates with an excessive amount of surface coverage by species with reactive functional groups would be expected to result in steric crowding of the reactive groups leading to a decrease in accessibility with respect to the subsequent grafting of vicinal biomolecules. Balancing the monomer ratio of reactive versus non-reactive groups would be an obvious means to control steric crowding.

In essence, it would have been obvious to a person of ordinary skill in the art at the time of the invention to have formulated a mixture of monomers with and without

Art Unit: 1786

reactive groups to control steric crowding to ensure that a suitable percentage of reactive groups were accessible during the subsequent grafting of vicinal bio-molecules.

6. **Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand (WO 2002/098926) in view of Crispin (J. Am. Chem. Soc., 1999, Vol. 121, pages 176-187) and Stirling (Advanced Materials, 2000, 12, No. 16, p. 1161-1171) and further in view of Fukuchi (US 4,691, 045).**

7. **Regarding Claim 27**, Bertrand, Crispin and Stirling teach the invention of claim 25. Bertrand also teaches the use of lactones and lactides such as (ε-caprolactone), and functional caprolactones such as γ-bromo- ε-caprolactone, or lactide such as D, L-Lactide or any other polymerizable cyclic monomer such as cyclic anhydride (page 9, lines 1-4) as the species cleavable by nucleophilic attack.

It is understood in the art that materials such as lactones are susceptible to nucleophilic at the electronegative carbonyl group.

Bertrand fails to mention substituted ethylene oxides as the species cleavable by nucleophilic attack.

Fukuchi discloses that hydroxyl containing methacrylate materials react with oxygen containing cyclic compounds (column 18, lines 40-43) such as epoxy compounds and lactones (column 18, lines 67-68). The epoxy compounds include alkylene oxides such as propylene oxide (a substituted ethylene oxide) (column 19, lines 8-9). The hydroxyl containing methacrylate material that Fukuchi discloses

Art Unit: 1786

polyhydroxyethylacrylate) (column 18, lines 40-43) is the same as Bertrand (page 8, lines 18-20).

The examiner notes that applicant includes hydroxyethyl metacrylate as an example of Formula I which is used to react with Formula II (material cleavable by nucleophilic attack).

Fukuchi shows that the nucleophilic attack of oxygen containing cyclic compounds such as lactones and propylene oxides can be carried out by the same nucleophilic agent, namely a hydroxyl containing methacrylate material. As both oxygen containing cyclic compounds are cleavable by a reaction with the same hydroxyethyl methacrylate materials, these cyclic materials would be considered as functional equivalents.

As Bertrand teaches cleavable cyclic materials (lactones) and Fukuchi teaches cleavable cyclic materials (lactones and alkylene oxides), it would have been obvious to a person of ordinary skill in the art at the time of the invention to have used propylene oxide (a substituted ethylene oxide) in place of the lactones material since Fukuchi discloses that these oxygen containing cyclic materials are susceptible to nucleophilic from hydroxyethyl metacrylate materials and would thus be considered as functional equivalents, absent unexpected results.

Response to Arguments

Applicant argues that the prior art does not show electrografted monomers made from organic precursors such as acrylic acid and methacrylic acid.

The examiner counters that Bertrand discloses active monomers derived from acrylate and methacrylic monomers as discussed above in section 2.

Applicant argues that Bertrand never mentions that the monomers used for a polyaddition via ring polymerization have to bear protic groups.

The examiner counters Bertrand's preferred embodiment uses monomers based on Formula B-1 where X can be a prepolymer, an intermediate for polyaddition reaction, an anchoring group (inclusive of hydroxyl group) for attachment of a molecule having at least one functional group.

Bertrand further discloses that polyhydroxyethylacrylate (contains hydroxyl protic groups) can undergo controlled or uncontrolled ring opening polymerization (page 8, lines 16-31). This clearly shows that protic group containing electrografted species used in polyaddition via ring polymerization was known at the time of the invention.

Applicant argues that Bertrand only teaches an indirect means to immobilization.

The examiner again counters that Bertrand shows protic groups containing electrografted species (polyhydroxyethylacrylate) used in polyaddition via ring polymerization was known at the time of the invention. In addition, the examiner refers applicant to Formula B-1 above where X can also be an intermediate for polyaddition reaction or an anchoring group for attachment of a molecule having at least one

Art Unit: 1786

functional group. The examiner views these features as a clear teaching of the direct immobilization approach.

With respect to accessible functional groups and the density of the functional groups of interest, Stirling clearly discloses that steric crowding play a critical role in decreasing functional groups reactivity.

It would have been obvious in the electrografting process to adjust the level of the "functional group containing species" which would affect the density of such species in order to account for the expected steric constraints (crowding of the functional groups limit reactivity) to produce the desired percentage of functional group accessibility and the ultimate density of the reactive groups.

As the prior art teaches the grafting of bio-molecules that are the same or in similar categories to those claimed by the applicant, it would have been obvious to one of ordinary skill in the art at the time of the invention to have conducted routine experiments to determine the appropriate level of reactive group containing monomer to ensure a suitable level of grafting which would have included the claimed accessibility and density ranges.

Sequence Rule Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons. Sequences appear at page 38, line 15,

Art Unit: 1786

page 42, lines 14 and 20 and a paper copy of a sequence listing was submitted December 23, 2004 but no computer readable form has been submitted.

Help with compliance with the sequence rules is available from Robert Wax, SPE of Art Unit 1615 whose number is (571) 272-0623.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY CLARK whose telephone number is (571)270-7087. The examiner can normally be reached on M-Th 7:00 AM to 5 PM Alternating Fri 7:30 AM to 4 PM and Off.

Art Unit: 1786

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1786

/GREGORY CLARK/GDC/
Examiner, Art Unit 1794

Application/Control Number: 10/518,923
Art Unit: 1786

Page 13